CLAIMS

1. A pharmaceutical composition comprising desglymidodrine or a pharmaceutically acceptable salt thereof together with one or more pharmaceutically acceptable excipients.

2. A composition according to claim 1, wherein desglymidodrine is selected from the group consisting of (±)-α-(aminomethyl)-2,5-dimethoxy-benzenemethanol (± ST 1059), (+)-α-(aminomethyl)-2,5-dimethoxy-benzenemethanol (+ ST 1059), (-)-α-(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059), or mixtures thereof.

3. A composition according to claim 1, wherein desglymidodrine is present in the racemic form (RS), in the enantiomeric form (R), in the enantiomeric form (S) or in mixtures thereof.

4. A composition according to claim 3, wherein the therapeutically active enantiomeric form of desglymidodrine is (-)-α-(aminomethyl)-2,5-dimethoxy-benzenemethanol (- ST 1059) or the (R) form of desglymidodrine ((R) ST 1059).

5. A composition according to any of the preceding claims, wherein at least 90% w/w such as, e.g., at least 95% w/w, at least 97% w/w, at least 98% w/w, at least 99% w/w of desglymidodrine is present in the therapeutically active enantiomeric form.

6. A composition according to any of the preceding claims, wherein desglymidodrine is present in the form of a pharmaceutically acceptable salt such as a salt formed between desglymidodrine and an inorganic acid such as e.g., a hydrochloride, a hydrobromide, a hydroiodide, a nitrate, a nitrite, a H_3PO_3 salt, a H_3PO_4 salt, a H_2SO_3 salt, a sulfate, a H_2SO_5 salt, or a salt formed between desglymidodrine and an organic acid such as organic acids like e.g. H_2CO_3, acetic acid, C_2H_5COOH, C_3H_7COOH, C_4H_9COOH, $(COOH)_2$, $CH_2(COOH)_2$, $C_2H_5(COOH)_2$, $C_3H_6(COOH)_2$, $C_4H_8(COOH)_2$, $C_5H_{10}(COOH)_2$, fumaric acid, maleic acid, lactic acid, citric acid, tartaric acid, ascorbic acid, benzoic acid, salicylic acid and phthalic acid.

7. A composition according to any of the preceding claims for oral, buccal, rectal, nasal, topical, vaginal, ocular or parenteral use.

8. A composition according to any of the preceding claims in the form of a solid, semi-solid or fluid composition.

9. A composition according to claim 8 in solid form, wherein the composition is in the form of tablets such as, e.g. conventional tablets, effervescent tablets, coated tablets, melt tablets or sublingual tablets, pellets, powders, granules, or particulate material.

10. A composition according to claim 8 in semi-solid form, wherein the composition is in the form of a chewing gum, an ointment, a cream, a liniment, a paste, a gel or a hydrogel.

11. A composition according to claim 8 in fluid form, wherein the composition is in the form of a solution, an emulsion, a suspension, a dispersion, a liposomal composition, a spray, a mixture, or a syrup.

12. A composition according to any of claims 1-7 in the form of a delivery device such as, e.g. a lens, a plaster, an implant or a bioadhesive device.

13. A composition according to any of claims1-11 in unit dosage form such as, e.g., a multiple unit dosage form or a single unit dosage form.

14. A composition according to claim 13, wherein the unit dosage form comprises a daily dose or a part of a daily dose of desglymidodrine.

15. A composition according to any of the preceding claims comprising one or more further active drug substances and/or one or more enhancers.

16. A composition according to claim 15, wherein the further active drug substance is midodrine or a pharmaceutically acceptable salt thereof.

17. A composition according to claim 15, wherein midodrine is present in the form of (±)-2-amino-N-(β-hydroxy-2,5-dimethoxyphenethyl)acetamide, (+)-2-amino-N-(β-hydroxy-2,5-dimethoxyphenethyl)acetamide, (-)-2-amino-N-(β-hydroxy-2,5-dimethoxyphenethyl)acetamide or mixtures thereof.

18. A composition according to claim 15, wherein midodrine is present in the racemic form (RS), in the enantiomeric form (R), in the enantiomeric form (S) or in mixtures thereof.

19. A composition according to claim 18, wherein the therapeutically active enantiomeric form of midodrine is (-)-2-amino-N-(β-hydroxy-2,5-dimethoxyphenethyl)acetamide or the (R) form of midodrine.

20. A composition according to claim 18 or 19, wherein at least 90% w/w such as, e.g., at least 95% w/w, at least 97% w/w, at least 98% w/w, at least 99% w/w of midodrine is present in the therapeutically active enantiomeric form.

21. A composition according to claim 9, wherein the composition is in the form of tablets having a disintegration time of at the most about 2.5 min such as, e.g at the most about 30 sec, at the most about 45 sec, at the most about 1 min, at the most about 1.5 min or at the most about 2 min.

22. A composition according to any of the preceding claims, wherein the composition has a shelf-life at room temperature of at least 6 months such as, e.g. at least 1 year, at least 1.5 years, at least 2 years, at least 2, 5 years, 3 years, 4 years or 5 years.

23. A composition according to any of the preceding claims, wherein the release kinetics of desglymidodrine from the composition corresponds to that of a plain release tablet.

24. A composition according to any of the preceding claims, wherein the release kinetic of desglymidodrine from the composition corresponding to a zero or a first order release, a mixture of zero and first order release, or any other order of release such as, e.g. 1½, second, third or fourth order release.

25. A composition according to any of the preceding claims, wherein the composition is adapted to release desglymidodrine in such a manner that a relatively fast therapeutic effective concentration of desglymidodrine is obtained after administration of the composition.

26. A composition according to claim 25, wherein the composition is adapted to release desglymidodrine relatively fast in order to obtain an onset of action at the most 15 min

after administration such as, e.g. at the most about 1 min, at the most about 2 min, at the most about 3 min, at the most about 4 min, at the most about 5 min, at the most about 7.5 min, at the most about 10 min or at the most about 12.5 min after administration.

27. A composition according to claim 25, wherein the therapeutically effective concentration is obtained within 90 min such as, e.g. within 60 min, within 45 min, within 30 min, within 20 min, within 15 min, within 10 min, within 5 min from administration of the composition.

28. A composition according to claim 25, wherein a relatively fast peak plasma concentration of desglymidodrine is obtained about 1 min - 6 hours such as, e.g. about 5 min – 6 hours, about 10 min – 5 hours, about 15 min – 5 hours, about 0.5-6 hours, about 1-6 hours, about 2-5.5 hours, or about 2.5-5.2 hours after administration.

29. A composition according to any of claims 1-24, wherein the composition is a controlled release composition.

30. A composition according to claim 29, wherein the composition is adapted to provide desglymidodrine in such a manner that a therapeutically effective concentration of desglymidodrine is maintained for at least about 2 hours after administration such as, e.g. at least about 3 hours, at least about 4 hours, at least about 5 hours, at least about 6 hours, at least about 7 hours, at least about 8 hours or at least about 9 hours after administration.

31. A composition according to claim 29, wherein the composition is adapted to release desglymidodrine in such a manner that a therapeutically effective plasma concentration of desglymidodrine is maintained for about 4.5-14 hours such as, e.g. about 6-14 hours, about 7-14 hours, about 8-13 hours, about 9-13 hours, about 10-14 hours, about 10-13 hours, or for at least about 4.5 hours, at least about 5 hours, at least about 6 hours, at least about 7 hours, at least about 8 hours, at least about 9 hours, at least about 10 hours, at least about 11 hours, at least about 12 hours, at least about 13 hours or at least about 14 hours.

32. A composition according to claim 31, wherein the plasma concentration of desglymidodrine from the controlled release composition is maintained at a relatively

constant level for about 4.5-16 hours such as, e.g., 6-14 hours or such as, e.g. for at least about 5 hours, at least about 6 hours, at least about 7 hours, at least about 8 hours, at least about 9 hours, at least about 10 hours, or at least about 11 hours.

33. A composition according to claim 32, wherein the relatively constant level n is ± 60%, such as, e.g., n ± 50%, n ± 40%, and wherein n is the plasma concentration in ng/ml and monitored in healthy persons.

34. A composition according to any of claims 29-33, wherein the release pattern of desglymidodrine from the controlled release composition - when tested *in vitro* using Dissolution Method I, II, III, IV, V or VI described herein - is:

1-15% w/w is released from the composition within the first 30 min after start of the test,
10-35% (25%) w/w is released about 30 min after start of the test,
15-40% (35%) w/w is released about 1 hour after start of the test
20-50% (39%) w/w is released about 2 hours after start of the test,
20-55% (47%) w/w is released about 3 hours after start of the test,
25-75% such as, e.g., 25-65% (53%) w/w is released about 4 hours after start of the test,
30-74% (66%) w/w is released about 6 hours after start of the test,
40-95% w/w such as, e.g., 45-85% (80%) w/w is released about 8 hours after start of the test,
65-100% (93%) w/w is released about 10 hours after start of the test,
75-110% (100%) w/w such as, e.g. 90-110% w/w is released about 12 hours after start of the test.

35. A composition according to any of claims 29-34, wherein the composition contains midodrine or a pharmaceutically acceptable salt thereof and wherein the release rate of midodrine from the controlled release composition follows the patterns claimed for desglymidodrine in claim 34.

36. A composition according to claim 29, wherein the composition contains midodrine or a pharmaceutically acceptable salt thereof and wherein the release rate from the controlled release composition of the sum of midodrine and desglymidodrine calculated on a molar basis follows the patterns claimed for midodrine in claim 34.

37. A composition according to claim 29, wherein the controlled release composition comprises at least two parts such as at least a first and a second part, each part contains desglymidodrine and the first part being adapted to release desglymidodrine in a controlled manner during the first 0-14 such as, e.g. 0-11 hours or 0-8 hours after oral intake and the second part being adapted to release desglymidodrine, starting at least 6 hours after oral intake.

38. A composition according to claim 37, wherein at least one of the at least two parts is present in the composition in the form of a multiplicity of individual units such as, e.g. pellets or minitablets.

39. A composition according to claim 37, wherein the two parts of the at least two parts are present in the composition in the form of a multiplicity of individual units such as, e.g. pellets or minitablets, and the two parts are in admixture.

40. A composition according to claim 37, wherein at least one of the at least two parts comprising at least two different types of pellets, the first type of pellets corresponding to a first fraction and the second type of pellets corresponding to a second fraction.

41. A composition according to claim 37, wherein the at least two parts of the composition comprise at least two different types of pellets, the first type of pellets corresponding to the first part and the second type of pellets corresponding to the second part.

42. A composition according to claim 37 in the form of a multiple unit dosage form comprising at least two different types of minitablets, the first type of minitablets corresponding to the first part and the second type of minitablets corresponding to the second part.

43. A composition according to claim 37 further comprising a third part adapted to release desglymidodrine relatively fast from the composition.

44. A composition according to claim 37 further comprising a fourth part adapted to release desglymidodrine from the composition 6-10 hours after administration.

45. A composition according to claim 37 further comprising a fourth part adapted to release desglymidodrine from the composition in the colon after oral intake.

46. A pharmaceutical kit comprising a composition according to any of claims 25-28 and a controlled release composition according to any of claims 29-45.

47. A pharmaceutical kit according to claim 46, comprising

iii) a relatively fast onset pharmaceutical composition according to any of claims 25-28, wherein the composition is adapted to provide desglymidodrine in such a manner that a relatively fast therapeutically effective concentration of desglymidodrine is obtained after administration, and

iv) a controlled release pharmaceutical composition according to any of claims 29-45, wherein the composition is adapted to release desglymidodrine in such a manner that a therapeutically effective plasma concentration of desglymidodrine is maintained for at least about 2 hours, such as, e.g. at least about 3 hours, at least about 4 hours, at least about 5 hours, at least about 6 hours, at least about 7 hours, at least about 8 hours or at least about 9 hours.

48. A pharmaceutical kit according to claims 45 or 46, wherein the relatively fast onset pharmaceutical composition is selected from the group consisting of: oral solid dosage forms, nasal compositions, parenteral compositions, liquid compositions and the like, and the controlled release pharmaceutical composition is selected from the group consisting of oral solid dosage form, transdermal compositions, parenteral composition, vaginal compositions, ocular compositions and the like.

49. A kit according to any of claims 46-48, wherein the relatively fast onset composition or part of the kit results in a peak or shoulder plasma concentration within 90 minutes such as, e.g., within 60 minutes, within 45 minutes, within 30 minutes, or within 20 minutes upon administration of the relatively fast onset composition.

50. A kit according to any of claims 46-49, wherein the relatively fast onset composition is a nasal composition.

51. A kit according to claim 50, wherein the nasal composition comprises polyethyleneglycol and/or glycofurol as a nasal vehicle.

52. A kit according to claim 51, wherein the polyethyleneglycol is PEG 200 and/or PEG 300.

53. A kit according to any claims 46-52, wherein the relatively fast onset composition is in the form of a liposomal composition.

54. A kit according to any of claims 46-49, wherein the relatively fast onset composition is in the form of tablets such as, e.g., melt tablets or sublingual tablets.

55. A kit according to any of claims 46-49, wherein the relatively fast onset composition is a buccal, oral, or rectal composition.

56. A kit according to any of claims 46-55, wherein desglymidodrine in relatively fast onset composition is present in an amount of from 0.2 mg to 10 mg, preferably from 0.5 mg to 7.5 mg such as in an amount of 0.75 mg, 1 mg, 1.25 mg, 1.5 mg, 2 mg, 2.5 mg, 3 mg, 4 mg or 5 mg.

57. A pharmaceutical kit comprising

iii) a relatively fast onset pharmaceutical composition comprising midodrine, wherein the composition is adapted to provide midodrine in such a manner that a relatively fast therapeutically effective concentration of midodrine is obtained after administration, and

iv) a controlled release pharmaceutical composition according to any of claims 29-45, wherein the composition is adapted to release desglymidodrine in such a manner that a therapeutically effective plasma concentration of desglymidodrine is maintained for at least about 2 hours, such as, e.g. at least about 3 hours, at least about 4 hours, at least about 5 hours, at least about 6 hours, at least about 7 hours, at least about 8 hours or at least about 9 hours.

58. A pharmaceutical kit comprising

iii) a relatively fast onset pharmaceutical composition according to any of claims 25-28, wherein the composition is adapted to provide desglymidodrine in such a manner that a relatively fast therapeutically effective concentration of desglymidodrine is obtained after administration, and

iv) a controlled release pharmaceutical composition comprising midodrine, wherein the composition is adapted to release midodrine in such a manner that a therapeutically effective plasma concentration of midodrine is maintained for at least about 2 hours, such as, e.g. at least about 3 hours, at least about 4 hours, at least about 5 hours, at least about 6 hours, at least about 7 hours, at least about 8 hours or at least about 9 hours.

59. A method for treating a patient suffering from orthostatic hypotension and/or urinary incontinence such as urinary stress incontinence, the method comprising administering an effective amount of desglymidodrine in the form of pharmaceutical composition according to any of claims 1-58 to a patient in need thereof.

60. A method according to claim 59, wherein an administration of the composition takes place at wake-up time.

61. A method according to claim 59, wherein an administration of the composition takes place in the morning.

62. A method according to claim 59, wherein an administration of the composition takes place at in the middle of the day and in the form of 1-2 tablets.

63. A method according to any of claims 59-62, wherein the administration takes place 1-3 times daily.

64. A method according to any of claims 59-62, wherein the administration takes place 1 or 2 times daily.

65. A method according to any of claims 59-62, wherein the administration takes place once daily.

66. A method according to any of claims 59-62, wherein the administration of the relatively fast onset composition takes place 1- 6 times daily.

67. A method for treating a patient suffering from septic shock, the method comprising administering an effective amount of desglymidodrine in the form of pharmaceutical composition according to any of claims 1-58 to a patient in need thereof.

68. A method according to claim 67, wherein the composition is adapted for parenteral administration.

69. A method according to claims 67 and 68 further comprising a supplemental administration of a composition according to any of claims 1-59.

70. Use of desglymidodrine or a pharmaceutically acceptable salt thereof for the manufacture of a pharmaceutical composition for the treatment of septic shock.

71. A method for treating a patient suffering from a condition responsive to α_1 receptor stimulation, the method comprising administering an effective amount of desglymidodrine in the form of pharmaceutical composition according to any of claims 1-58 to a patient in need thereof.

72. Use of desglymidodrine or a pharmaceutically acceptable salt thereof for the manufacture of a pharmaceutical composition for the treatment of a condition responsive to α_1 receptor stimulation.

73. A method for treating a patient suffering from syncope, the method comprising administering an effective amount of desglymidodrine in the form of pharmaceutical composition according to any of claims 1-58 to a patient in need thereof.

74. Use of desglymidodrine or a pharmaceutically acceptable salt thereof for the manufacture of a pharmaceutical composition for the treatment of syncope.

75. Use of desglymidodrine or a pharmaceutically acceptable salt thereof for the manufacture of a pharmaceutical composition for the treatment of urinary incontinence such as urinary stress incontinence